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ORIGINAL ARTICLE

Surgical glove bacterial contamination and perforation during total hip arthroplasty implantation: When gloves should be changed

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KEYWORDS

Replacement of the
hip joint;
Asepsis;
Glove perforation

Summary

Introduction: Double gloving is recommended in orthopedic surgery, notably in total hip arthroplasties (THA) to prevent contamination of the surgical site.

Hypothesis: Systematic glove changes during the key phases of hip prosthesis implantation reduce the frequency of occult perforations and bacterial loading of glove surfaces.

Patients and methods: During 29 THA implantation procedures, we evaluated the bacterial contamination of the outer glove surface and its perforation rate. Contaminations were sought by placing the gloved fingertips on blood gels (incubation, 48 h at 37 °C), and perforations were sought using a water test (NF EN 455-1).

Results: One intervention was excluded from the study because an initial contamination was detected, leaving 28 cases analyzed. Fifteen interventions (53.6%) presented contaminated gels (26 contaminated glove changes for 3.38% of the gloves used). These contaminations were found on the gloves of all of the gloved personnel, with no distinction as to the right or left side. Thirty-eight percent of the contaminations occurred during joint reduction, whereas the other surgical stages grouped 15–26% of the contaminations ($P < 0.05$). Twenty-nine bacteria were identified: 62% coagulase-negative staphylococci (16% of which were methicillin-resistant). Twenty-eight perforations were identified (3.5% of the gloves used), 67.8% of which were located on the operator and 64.3% on the dominant side. Eighty percent of the perforations occurred during the “surgical incision” and the “cup and stem implantation” stages (respectively, 5.0% and 5.5% of the gloves used during the surgical time) ($P < 0.05$), without being associated with an increased risk of bacterial contamination. At the 12-month clinical follow-up, no infectious complications were found. On the gloves worn by the 20 surgical team

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members contaminated during these 28 surgical procedures, replacing contaminated gloves with new sterile gloves rendered all the bacteriological samples of the subsequent surgical stages negative in 16 cases (80%).

Discussion: Increasing the number of outer glove renewals, notably during certain surgical stages at risk for contamination (prosthesis reduction) or perforation (surgical incision/femoral cementing) can reduce the risk of contamination and perforation. The bacteria isolated suggest a cutaneous origin. Regularly changing gloves has resulted in a sterile state in 80% of cases.

Level of evidence and type of study: Level III prospective diagnostic study.

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Introduction

Forty years ago, implantation of a total hip prosthesis (TKA) was marked by a 7% infection rate at 6 months [1]. Sir John Charnley understood at the time that reducing infections required improving practices in the operating room where contamination took place. Surgical asepsis, the use of laminar flow, antibiotic prophylaxis, as well as cutaneous preparation [2] have greatly decreased intraoperative bacterial contamination, thus reducing the postoperative infection rate, currently around 1% [3,4]. Surgical gloving is the showpiece of this asepsis, ensuring the prevention of cutaneous bacteria from the wearer in the surgical field as well as protecting the surgical team from the patient's biological fluids. Use of double gloving is a recommended practice [5–8], yet the modalities of glove change and its frequency have not been included in any scientific guidelines.

To determine whether there is a mechanical (perforation) or bacterial (contamination) value to changing gloves at certain times during this procedure, we studied bacterial contamination of the outer glove surface and their perforation rate during 29 THAs. We hypothesized that systematically changing the outer gloves at certain times during the intervention would reduce the frequency of occult perforations (protecting the operator) and reduce the bacterial load at the surface of the gloves, thus preventing contamination of the surgical site.

Patients and methods

Patients

The study was conducted at the Rouen University Hospital (France) from March 2010 to July 2010 on implanting 29 primary THA prostheses (10 males, 19 females; mean age, 63 years [range, 43–81 years]) who consecutively received implants in the operating room. The sole operator (F.D.), a senior surgeon in hip surgery, was assisted by an assistant and a scrub nurse for a mean surgical time of 50 min.

In 16 cases, the acetabular implants were polyethylene-cemented cups, in 11 cases, dual mobility cups, and in two cases metal-back cups. On the femoral side, the stems in 26 cases were Charnley-type cemented monobloc stems and in two a cemented modular pivot, and in one a locked pivot. The approach was the Thomine anterolateral approach (anterior hemimiotomy) in 23 cases and posterolateral in six cases.

The gloves used were double Gammex PF gloves (Ansell™, Ansell Healthcare LLC™, Red Bank, NJ, USA) for the entire surgical team. The protocol did not change the surgical habits of the operator or the arthroplasty conditions except for the presence of two individuals in the operating room in charge of ensuring that the protocol was followed (Table 1). Each intervention was broken down into five surgical stages before and/or after which the outer gloves were changed (Fig. 1). The inner gloves were never changed except for visible perforation.

Table 1 Protocol identical to the operator's surgical habits or arthroplasty conditions.

Operating room

An orthopaedic operating room dedicated to prosthetic surgery, including horizontal laminar flow (renewal rate, 117 volumes/h)

Anesthetic induction as well as patient installation in the operating room

Cutaneous cleaning

Betadine scrub® except in cases of allergy

First skin prep (Betadine alcoolique® except in cases of allergy) carried out by scrub nurse

Second skin prep carried out by dressed surgical team

Dressing

Disposable sterile gowns, impermeable and reinforced (Allegiance® Healthcare Corporation, McGraw Park, IL, USA), without surgical face mask or sterile cap

Draping

Disposable draping including the entire limb from the gluteal region to the foot ("hip pack" from Allegiance™ Healthcare Corporation, McGraw Park, IL, USA)

A permeable stocking for the operated limb during hip dislocation (inclined position under the table level during lateral approaches). The stocking was changed during reduction before replacing limb on the operating table

Antibiotic prophylaxis

According to the Société Française d'Anesthésie Réanimation guidelines (SFAR 1992 updated in 1999) and the institution's committee for controlling nosocomial infections

Administration of 1.5 g preoperative cefuroxime then 0.75 g/6 h for 48 h (except in cases of particular allergy)

For cemented implants, use of bone cement with gentamicin (Palacos® R + G high-viscosity, Heraeus Medical GmbH, Wehrheim, Germany)

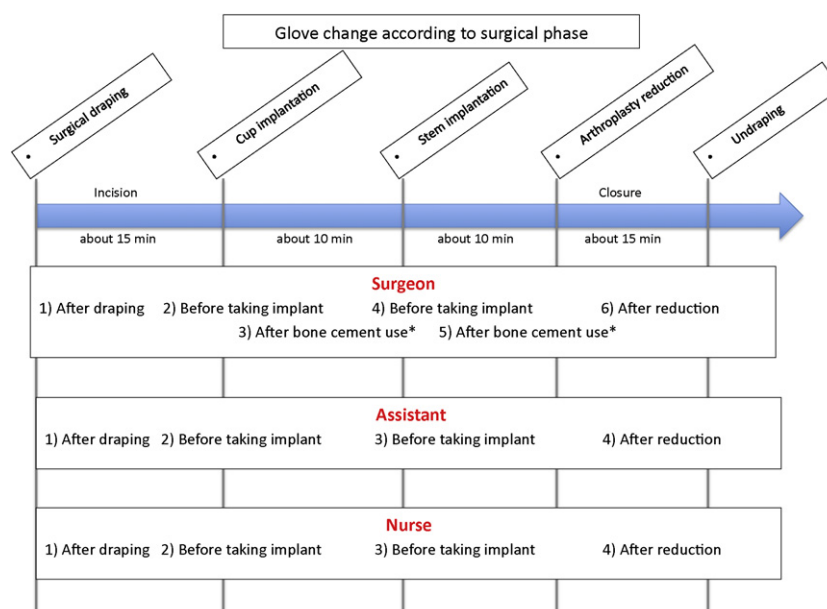


Figure 1 Outer glove change modality for each surgical team member and the different surgical phases. To facilitate the analysis of the results, glove changes were distributed into the four key stages of the intervention: 1) draping, 2) the surgical incision and bone preparation (acetabular + femoral), 3) both implantation phases (cup and stem) were merged into a single “cup + stem implantation” phase, grouping the changes, 4) the “reduction and closing” phase. *Optional phase for cemented implants.

Methods

Glove analysis included two search phases (Fig. 2): a bacterial contamination study of the outer gloves before glove change by placing the five fingers of each hand on a culture dish; the search for outer glove perforations using a water test.

Search for bacterial contamination of the outer gloves

The five fingertips of each hand were placed on a bacteriological culture medium (one gelose per hand), before the outer glove was replaced with a new one. Twenty-eight geloses were seeded for every intervention (for the cemented implants). An unopened control dish (negative control) was added at the end of the intervention, demonstrating that the batch had not been bacteriologically contaminated during its transport. The geloses used were Columbia agar with horse blood (BioMérieux, Marcy l'Étoile, France), incubated 48 h in an aerobic atmosphere at 37°C. The presence of bacteria was identified and counted as the number of colony-forming units (CFU) per dish, with each colony producing an antibiogram (using the gelose diffusion method) and identification of the genus and species. The frequency of coagulase-negative staphylococci and the usual problems with the biochemical identification of these staphylococci led us to identify all these bacteria using molecular sequencing of a PCR-amplified 16S DNA fragment. We did no anaerobic cultures because the procedure is lengthy, a large number of incubated dishes are necessary, and the technical conditions are highly demanding.

Search for outer glove perforation

The used outer gloves were preserved in a non-sterile environment to analyze their perforations by reproducing the

technical conditions of the NF EN 455-1 European norm (Fig. 3). Fourteen pairs of gloves were analyzed per intervention (for a cemented THA on both sides).

Statistical analysis

The frequency of the contaminations and perforations was analyzed statistically using SPSS software (Kaysville, UT, USA) using the χ^2 test with a 5% significance threshold.

Results

To facilitate the analysis of the results, the gloves were divided into the four key stages of the intervention: “draping,” “surgical incision and bone preparation,” “cup and stem implantation,” and “reduction and closing” (Fig. 1).

Bacteriological results

All the control geloses were found to be negative except for one. The intervention in which this contaminated gelose was used was therefore excluded from the bacteriological study. Consequently, the results reflect 28 interventions (769 gloves) during which the geloses of 26 glove changes were contaminated. For 13 of the 28 interventions, the incubation of the geloses was negative. Fifteen of 28 interventions presented contaminated geloses (53.6%), for a total of 26 contaminated glove changes, randomly distributed throughout the study. Ten interventions presented a single contaminated glove change, whereas the six others consisted of at least two. The bacterial inoculum comprised one CFU per intervention out of eight interventions, whereas the

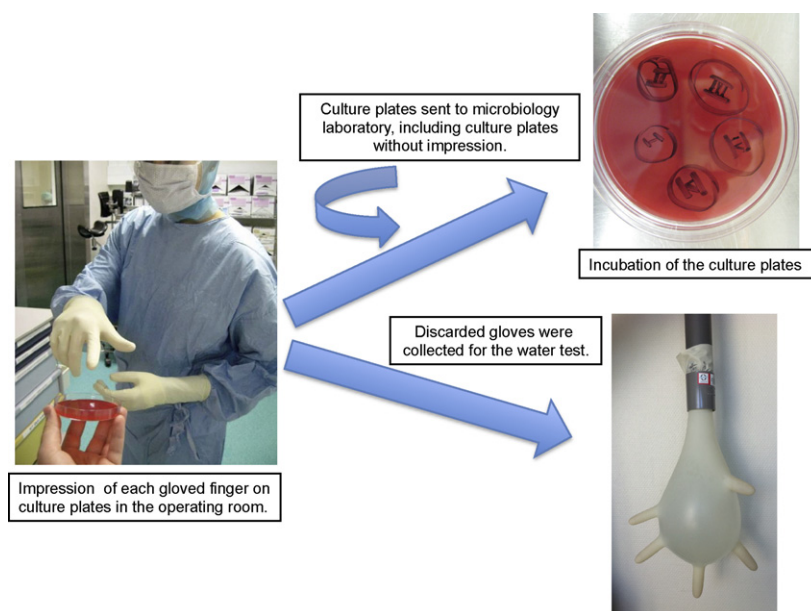


Figure 2 Protocol for gloves used.

seven others included up to five CFUs per intervention. The joint reduction stage contained the highest proportion of positive gloves (38% of the contaminated gloves) (Table 2). Analyzed as the number of contaminations in relation to the number of gloves used, this surgical stage accounted for 6.09% of the contaminated gloves versus a mean 3.38% over all the surgical stages. This predominance was not significant when counting the surgical stages one by one. However, the reduction stage compared to the three other surgical stages combined showed contamination significantly more often ($P < 0.05$).

The 26 contaminated glove changes came from all gloved surgical team members (operator, scrub nurse, and assistant): the assistant and the scrub nurse were contaminated (one or several CFUs) seven and eight times, respectively (out of four samples per intervention), whereas the operator was contaminated 11 times (out of six samples per intervention). In 13 cases, these contaminations came from the dominant hand of the personnel versus in 13 instances from the non-dominant side.

The bacterial load was low, since the 29 bacteria isolated corresponded to 34 CFUs. The 29 bacteria consisted of 62% coagulase-negative staphylococci (CNS), 20% *Micrococcus* spp., and 13% *Bacillus* spp. (Table 3). The CNSs were for the most part methicillin-sensitive (15/18), whereas three strains were methicillin-resistant. For seven interventions presenting repeated contaminations, in six cases the bacteria belonged to the same genus (CNS, *Micrococcus*, *Bacillus*), but precise identification of the species (using molecular sequencing) confirmed that the same bacterium was involved (identical genotype) in four out of six cases. Therefore, within the repeated contaminations during the same intervention, four out of seven were recontaminations (identical species) and three out of seven were new contaminations (different species). On the gloves of the 20 contaminated surgical team members during these 28 interventions, exchanging contaminated gloves for new sterile gloves rendered all the bacteriological samples negative in 16 cases (80%) in the following surgical stages.

Table 2 Percentage of contaminated gloves versus number of gloves used for each surgical stage.

Surgical stages	Number of contaminations (%)	Number of gloves studied	% Gloves contaminated
Draping	5 (19.2)	163	3.06
Incision and bone preparation	4 (15.3)	176	2.27
Cup + stem implantation	7 (26.9)	266	2.63
Reduction	10 ^a (38.4)	164	6.09 ^a
Total	26 (100)	769 ^b	3.38

^a The distribution of contaminations did not significantly differ (Chi² test, $P > 0.05$) when comparing surgical stages one by one. However, the "reduction" stage compared to the three other surgical stages combined showed significantly more frequent contaminations (Chi² test, $P < 0.05$).

^b For the contaminations, only 769 gloves were statistically analyzed (because one intervention was excluded for one contaminated transport gelose). However, the gloves from this intervention were analyzed for perforations, with a total of 782 gloves analyzed.

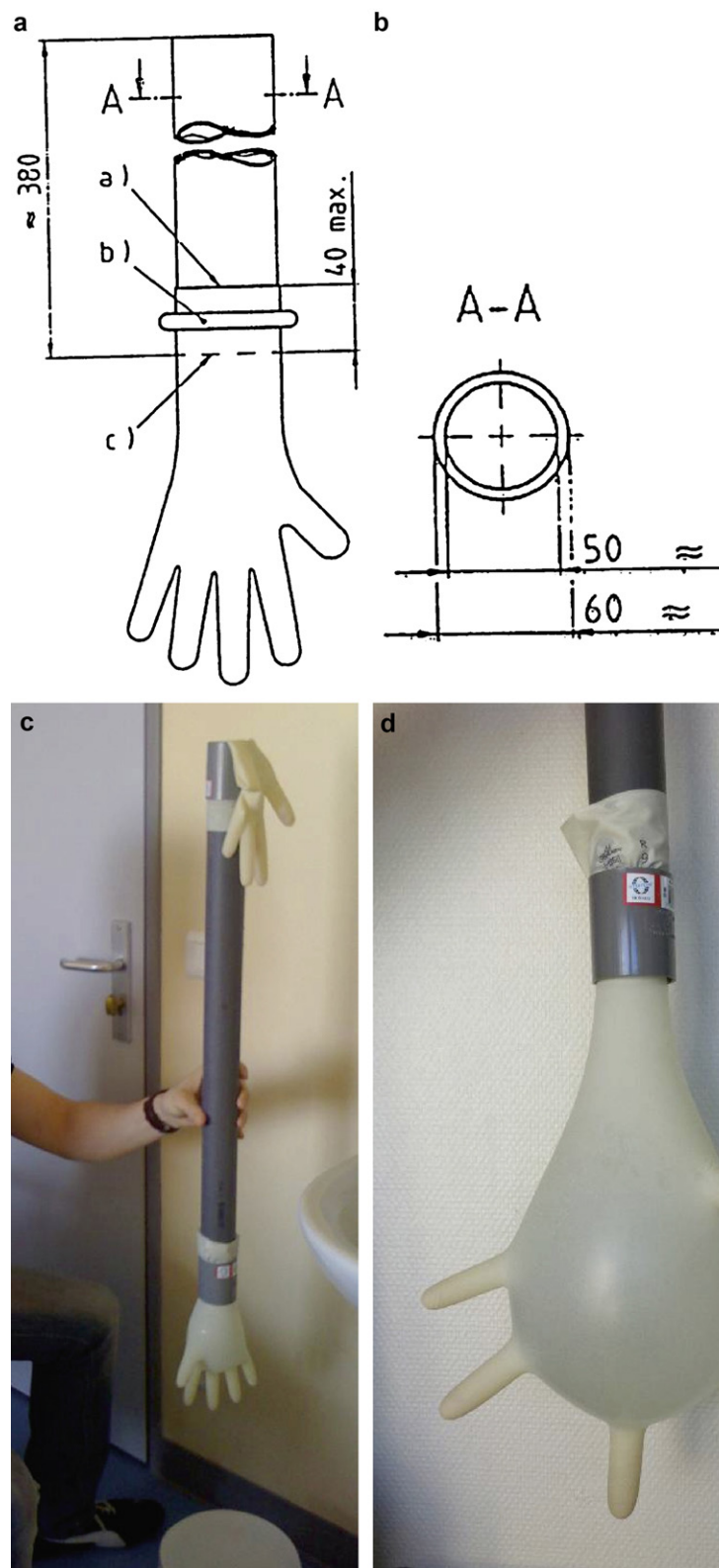


Figure 3 Perforation test. a and b: the 2001 NF EN 455-1 European norm is a permeability and mechanical resistance norm required of manufacturers, importers, and suppliers marketing disposable medical gloves. It requires that gloves sold must pass a specific permeability test: "absence of visually detectable leakage after 2–3 min when filled with 1 L of water distributed in a column 50 mm in diameter at a temperature between 15 and 35 °C"; c and d: Reproduction of the technical conditions detailed in the NF EN 455-1 norm in our laboratory using a PVC tube with a 50-mm interior diameter from which each glove was suspended for 2 min. Perforations appeared as a "small continuous stream of water" or "drop by drop" from the perforation point.

Table 3 Distribution of the 29 bacterial contaminations (34 CFUs) identified in our series.

Bacteria	Davis et al. [9]	Al-Maiyah et al. [10]	Our series
Coagulase-negative <i>staphylococcus</i>	86	73	18 ^a
<i>Staphylococcus aureus</i>	1	7	0
<i>Streptococcus</i> spp.	5		0
<i>Micrococcus</i> spp.	4	13	6
Coryniformis	2	10	1
<i>Bacillus</i> spp.	2		4
Coliforms		1	0
<i>Pseudomonas</i> spp.	4	2	0
Others	2 ^b		0

^a All METI-S except three methicillin-resistant *staphylococcus*.

^b One anaerobic diphtheroid and one *Pasteurella haemolytica*.

At the 12-month clinical follow-up, no surgical revision had been performed and no infectious complications were found clinically.

Results of the permeability test

The perforation tests (782 gloves from the protocol) identified 28 perforations (3.58%), all of which went unnoticed. For the most part, these perforations were found on the operator's gloves (67.8% of cases) (17.8% on the assistant's gloves and 14.3% on the scrub nurse's gloves). Eighteen involved the wearer's dominant side (64.3%) and 10 the non-dominant side (35.7%) (NS, $P > 0.05$). They were located on all fingers except the ring finger (Table 4); only on the palmar side for the long fingers and equally on the dorsal and palmar side for the thumb.

These perforations appeared during all surgical stages (Table 5). However, the "draping" and "reduction" stages accounted for less than 14% of the perforations, whereas the "surgical incision and bone preparation" and "cup and stem implantation" stages accounted for more than 80% of the perforations ($P < 0.05$). Brought to the number of gloves used, the frequency of perforations was 3.58% of all the gloves used in the series. The "incision and bone preparation" and "cup and stem implantation" stages resulted in a significantly higher perforation rate (respectively, 5.02% and 5.55% of the gloves during these stages were perforated). Dissociating the "cup and stem implantation" into "cup implantation" and "stem implantation" stages, we noted that a majority of the perforations took place during femoral

cementing compared to the acetabular stage (13/234 gloves used [5.5%] versus one perforation for 36 gloves used [2.7%]).

These perforations were not associated with a higher risk of positive biological samples: of the gloves of the 24 surgical team members that presented a perforation, 19 had no positive samples versus only five with both perforations and positive bacteriological samples ($P > 0.05$).

Discussion

The articles studying surgical glove contamination and perforations are recent [9,10]. Compared to these series, our study material was equivalent: the number of patients was lower but the study was more homogeneous (single center, single operator, a single type of intervention, with no modification in operator practices) with more frequent glove changes that allowed us to identify the times when gloves were contaminated or perforated. Moreover, this study assessed the relations between contaminations and perforations by separating them into the different surgical stages, which was not done in the previous studies [9,10]. Rather than changing gloves in relation to the duration of surgery [11,12], this study was based on the surgical stages for glove renewal so as to identify the at-risk surgical stages.

We used a bacteriological method that was comparable to the earlier publications [9,10]. However, it studied only the five fingertips (the major location for contaminations [9]) without seeking to demonstrate contaminations located on other parts of the gloves. The study is also original in that it identified the bacteria by molecular sequencing and compared their sensitivity to antibiotics, thus confirming the identify of the successive isolations in four cases. Contrary to Davis et al. [9], we chose not to search for anaerobic bacteria, because their isolation is laborious for bacteria that are rarely involved in infections on surgical material. Our culture was limited to 48 h, also identical to most of the previous studies [9,10], with, however, the bias of not being able to identify slow-growing bacteria (*Propionibacterium*, *Peptostreptococcus*, etc.), which may be responsible for late infections [13]. To assess perforations, the method used in this study was comparable to that used by Al-Maiyah et al. [10], Chan et al. [14], and Harnoss et al. [11], reproducing the EN-445 European norm (the water test). This method seems more effective than the method simply filling the

Table 4 Distribution of perforations in relation to location (independent of side).

Location of perforations	Number	%
Thumb	5	17.8
Index finger	4	14.5
Middle finger	6	21.4
Ring finger	0	0
Little finger	7	25
Palm of the hand	6	21.4
Total	28	100

Table 5 Percentage of gloves perforated versus number of gloves used for each surgical stage.

Surgical stages	Number of contaminations (%)	Number of gloves studied	% Gloves contaminated
Draping	3 (10.7)	166	1.80
Incision and bone preparation	9 (32.1) ^a	179	5.02 ^a
Cup + stem implantation	15 (53.5) ^a	270	5.55 ^a
Reduction	1 (3.5)	167	0.59
Total	28 (100)	782	3.58

^a The frequency of perforations was significantly higher for the "incision + bone preparation" and "cup + stem implantation" stages compared to the other surgical stages (Chi² test, $P < 0.05$).

glove with water [15–18]. Several studies have already demonstrated the frequency of bacterial contaminations during the surgical act [19–22]. In orthopaedics, Davis et al. [9] reported contaminations in 63% of interventions, which varied depending on the location. Al-Maiyah et al. [10] increased the number of glove changes, decreasing their rate of contaminated interventions from 76 to 44%. With 53.6% contaminated interventions and 3.38% positive gloves, this study showed one of the lowest contamination rates, notably because of the more frequent glove changes.

Separating the surgical stages allowed us to identify a higher frequency of contaminations during the reduction stage. This surgical stage, placing the lower limb on the table after initially placing it in an inclined position (also changing the dislocation stocking), therefore seems at risk. Davis et al. [9] found a 28.7% glove contamination rate for this same surgical stage. This risk, however, seems to vary depending on the type of dislocation (itself depending on the surgical incision) and how the dislocated limb is protected. In addition, the relatively high contamination rate during draping is surprising: given that it was the first stage of the procedure, we thought there would be little contamination. Yet for McCue et al. [23] and Davis et al. [9], this "limb sterilization" stage is a time when the laminar flow is disturbed, transforming the contaminated milieu into a clean milieu. Davis et al. [9] reported 20% glove contamination and advised changing gloves after draping and before application of a cutaneous adhesive. Brown et al. [24] found 2.4–4.4 times more air contaminations during patient preparation and draping than during the rest of the intervention, advising surgeons to open the instrumentation boxes only when draping had been completed. One of the features of the present study was that it showed the value of changing gloves so as to return to a "state of sterility" (achieved in 80% of cases for the same bacterium and lasting until the end of the intervention), whereas other authors only demonstrated a reduction in the incidence of contaminations by multiplying glove changes [10].

The type of bacteria identified (Table 3) was in accordance with previous publications [9,10], except for the absence of *Staphylococcus aureus* in the samples studied. The predominance of CNS was interesting, because this type of bacterium is involved in more than one-third of orthopaedic infections [25], but it is also worrisome because 16% of them were methicillin-resistant and were therefore not targeted by the antibiotic therapy. Identification of *Micrococcus* spp. or *Bacillus* spp. was less worrisome because these less virulent cutaneous bacteria frequently

contaminate culture media, are sensitive to antibiotics, and are found exceptionally as pathogenic agents. In a context of repeated contaminations, identification of the species using sequencing and comparison of antibiograms demonstrated a number of new contaminations by a new strain, comparable to the antibiogram of recontaminations from the same strain.

The source of these contaminations could be double: by air contamination or colonization by the patient's skin [26,27]. Cutaneous contamination from the patient is for some the greater part of deep contaminations [28]: this explains that Davis et al. [9] found 9.4% superficial contamination of scalpel blades versus 3.2% deep contamination of blades and found more glove contamination (directly in contact with the patient's skin) than the rest of the surgical instrumentation (collection bag, suction cannula, operating lamp handles, etc.). As for airborne contamination, it is proportional to the number of suspended particles and accounts for 80–90% of bacterial contaminations [26]. In the present study, demonstration of recontaminations by the same strain at different stages of the surgery and on different operators could suggest a persistent cutaneous source from the patient that had not been eradicated during patient preparation. The antibiograms showed substantial heterogeneity in bacterial strains, for the most part community-acquired, suggesting a cutaneous source rather than an operating room contamination, whose strains would have varied little and been more resistant [29]. At the 1-year follow-up, the absence of infectious complications on the surgical site underscores the fact that developing a postoperative infection is a much more complex complication depending on many other factors than those studied herein (bacterial inoculum, host–contaminant relationship, patient background, etc.).

The recent orthopaedic literature reports glove perforation rates oscillating between 3.6 and 21% [30], placing the results of this study among the lowest rates, similar to "non-bone" acts in orthopaedic surgery. This low rate could result from our habit of changing gloves more often than in other studies [10,23] or by our practitioner's experience in a first-line surgery. This rate cannot be explained by a particular glove thickness: Ansell's PF range has an intermediate thickness (0.20–0.25 mm). These perforations were not related to the manufacturing process because they were estimated at less than 1% by Ersozlu et al. [31] and Jamal et al. [30]. Perforations were not noted intraoperatively, confirming the results reported in the literature ranging from 58% [24] to over 80% of perforations not detected by the wearer [11,30].

The significant predominance of these perforations during the “surgical incision” and the “cup and stem implantation” confirmed that their source could be attributed to the instrumentation (torsion and shearing stress) and bone debris, as shown by Chan et al. [14], who found 45% perforations caused by instrumentation versus only 20% by bone debris, 15% surgical knots, and only 5% (each) attributable to scalpel blades or pins. These perforation mechanisms also explained their predominance on the operator (the main user of the instrumentation and the most exposed to bone debris) [10,14,31]. The location of the perforations (predominantly on the index and the thumb on the palmar side and on the non-dominant side) was comparable to what has been reported in the literature [5,6,14,30,32], except for a higher proportion on the palm and the ring finger. The location of these perforations can be explained by the use of cutting objects by the dominant hand (perforating the opposite hand), whereas rasps and sculpting objects were used by the non-dominant hand, with the projections directly in contact with the glove on the ulnar edge (gripping). The perforations located on the index finger during femoral sealing can be explained by the cementing method used (insertion of the index finger into the femoral shaft, rubbing against the bony reliefs of the medullary canal). The assistant’s and the scrub nurse’s perforations accounted for approximately one-third of the perforations and were found at all surgical stages, including draping, which was related to setting up and using the surgical instrumentation before the beginning of the intervention.

In the present study, these perforations did not themselves promote bacterial contaminations. The results of this study are therefore compatible with those reported by Misteli et al. [32] and Dodds et al. [15], who observed no relation between perforation and contamination. On the other hand, these perforations ruptured the protection against chemical solvents (cementing) [33–35].

Conclusions

More frequent renewal of outer gloves, notably during certain surgical stages with a high risk of bacterial contaminations (e.g., prosthesis reduction) or perforations (e.g., surgical incision and femoral cementing) resulted in lower contamination and perforation rates. The bacteria isolated suggest a cutaneous source. Based on these results, we recommend:

- renewing the entire team’s outer gloves after draping (before placing a cutaneous adhesive);
- the instrumentation is only opened secondarily, with a new glove change after handling the ancillary instrumentation that may cause perforations;
- outer gloves are then renewed after each surgical stage, with particular attention paid to:
 - the end of the bone preparation phase (risk of perforation on bony debris or the instruments used);
 - after reduction of the replaced joint (passing the limb from the inclined dislocated position to the reduced position on the surgical field, which is the phase with the most frequent contamination);
 - for the operator, additional glove changes are preferred after the cementing stage (for both risks of infection and exposure to solvents).

Disclosure of interests

There are no conflicts of interest for any of the authors, notably with Ansell (Ansell Healthcare LLCTM, Red Bank, NJ, USA).

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